K080755

JUN 10 2008

510(K) SUMMARY
Bausch & Lomb, Inc.
510(k) Premarket Notification
Bausch & Lomb® SofLens® daily disposable toric (hilafilcon B) Visibility Tinted Contact Lens

1. Applicant's Name and Address

Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609

2. Contact Person

Susan Pate
Associate Manager
Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609
(585) 338-6362
susan.m.pate@bausch.com

3. Identification of Device

Common Name:	soft contact lens (hydrophilic)
Trade Name:	SofLens® daily disposable toric (hilafilcon B) Visibility Tinted
Classification:	Daily Wear Contact Lens
Device classification:	Class II (21 CFR 886.5925)
Product Code:	MVN

Predicate Devices:

The predicate devices, SofLens daily disposable (hilafilcon B) and SofLens59 (hilafilcon B) Contact Lenses, were selected to demonstrate substantial equivalence of the lens material, hilafilcon B, and replacement modality, single-use disposable lens. The predicate device SofLens toric (alphafilcon A) Contact Lenses was selected to demonstrate substantial equivalence to the Bausch & Lomb toric lens design.

The SofLens daily disposable toric (hilafilcon B) Visibility Contact Lens is substantially equivalent to the currently marketed SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens cleared in 510(k) Premarket Notification No. K061158 on June 22, 2006, SofLens59 (hilafilcon B) Visibility tinted Contact Lens 510(k) Premarket Notification K994125 cleared on March 3, 2000 and SofLens Toric (alphafilcon A) Visibility Tinted Contact Lens 510(k) Premarket Notification No. K941370 cleared on April 2,1994.

The differences between the devices follow.

SIMILARITIES and DIFFERENCES

Feature	SofLens daily disposable toric	SofLens daily disposable	SofLens59	SofLens Toric
FDA Group	Group II (high water/non-ionic)	Group II (high water/non-ionic)	Group II (high water/non-ionic)	Group II (high water/non ionic)
Manufacturing Process	Castmolded	Castmolded	Castmolded	Castmolded
USAN Name	hilafilcon B	hilafilcon B	hilafilcon B	alphafilcon A
Indications	Toric Daily Wear	Spherical Daily Wear	Shperical Daily Wear	Toric Daily Wear
Modality	Single-use disposable	Single-use disposable	Frequent replacement	Single-use disposable or Frequent replacement
Design Properties				
Diameter	14.2mm	14.2mm	14.2mm	14.5mm
Center Thickness (-3.00D)	0.125mm	0.090mm	0.140mm	0.190mm
Base Curve	8.6mm	8.6mm	8.6mm	8.5mm
Sphere powers	Plano to -6.00D in 0.25D steps -6.50D to -9.00D in 0.50D steps	+6.50D to -6.50D in 0.25D steps -7.00D to -9.00D in 0.50D steps	+6.50D to -6.50D in 0.25D steps -7.00D to -9.00D in 0.50D steps	+6.00D to -6.00D in 0.25D steps -6.50D to -9.00D in 0.50D steps
Cylinder Powers	-0.75D, -1.25D, -1.75D	n/a	n/a	-0.75D, -1.25D, -1.75D, -2.25D and –2.75D
Axis	0^{o} to 180^{o} in 10^{o} Increments	n/a	n/a	0^{o} to 180^{o} in 10^{o} Increments
Aspheric Optics	Yes	Yes	No	No

4. Description of device

The SofLens® daily disposable toric (hilafilcon B) Visibility Tinted Contact Lens is a soft hydrophilic contact lens which is available in a toric lens design for the correction of astigmatism. The lens is made from the hilafilcon B material, a hydrophilic copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone, and is 59% water by weight when immersed in a sterile saline solution. This lens is tinted blue with Reactive Blue Dye 246.

5. Intended use

The SofLens® daily disposable toric (hilafilcon B) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, and astigmatism) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 5.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

6. Description of Safety and Substantial Equivalence

A series of preclinical and clinical studies were completed and previously submitted in Premarket Notifications K061157, K994125 and K941370.

Non-Clinical Laboratory Testing:

A series of *in vitro* and *in vivo* preclinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens material, hilafilcon B. Testing was performed in accordance with FDA guideline titled *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses*, May 1994. The non-clinical testing can be found in the currently marketed SofLens®59 (hilafilcon B) Visibility Tinted Contact Lens 510(k) Premarket Notification K994125 cleared on March 3, 2000.

Stability testing has demonstrated a five year expiration date for the sterile lenses.

Clinical Testing:

The clinical performance to confirm safety and effectiveness of the lens material, hilafilcon B, was conducted on the SofLens59 (hilafilcon B) Visibility Tinted Contact Lens and cleared in the Premarket Notification K994125 on March 3, 2000. The clinical performance to confirm the safety and effectiveness of the lens modality, daily disposable, was conducted on the SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens cleared under Premarket

Notification K061157 on June 22, 2006. The Bausch & Lomb toric contact lens design was cleared in the SofLens Toric (alphafilcon A) Visibility Tinted Contact Lens Premarket Notification K941370 on April 2, 1994.

7. Substantial Equivalence

The SofLens daily disposable toric (hilafilcon B) Visibility Tinted Contact Lens is substantially equivalent to the currently marketed SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens 510(k) Premarket Notification K061157 cleared on June 22, 2006; SofLens59 (hilafilcon B) Visibility Tinted Contact Lens 510(k) Premarket Notification K994125 cleared on March 3, 2000; and SofLens Toric (alphafilcon A) Visibility Tinted Contact Lens 510(k) Premarket Notification K941370 cleared on April 2, 1994. The lenses are similar in that all lenses fall into FDA Group II for soft (hydrophilic) contact lenses because the ionic content is less than 1% (nonionic polymer material), the water content is greater than 50% (hilafilcon B - 59% and alphafilcon A - 66%) and are manufactured with the same manufacturing process (cast molding).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bausch & Lomb, Inc.
c/o Ms. Debra Ketchum
Manager, Global Regulatory Affairs
1400 North Goodman St.
Rochester, NY 14609

JUN 10 2008

Re: K080755
Trade/Device Name: Bausch & Lomb® SofLens® Daily Disposable Toric (hilafilcon B) Visibility Tinted Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: MVN
Dated: March 14, 2008
Received: March 18, 2008

Dear Ms. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080755

Device Name: SofLens® daily disposable toric (hilafilcon B) Visibility Tinted Contact Lens

Indication for Use

The SofLens® daily disposable toric (hilafilcon B) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, and astigmatism) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 5.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

Prescription Use ____X_____ OR Over-the –counter-use_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K080755